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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,671	09/24/2001	Antonio Parente Duena	P/ 189-162	4516

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,671	Applicant(s) DUENA ET AL.	
	Examin r Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuisz (USPN 5518730) in view of Yamamoto et al (USPN 4954298), Bodmer et al (USPN 5538739), and Canal et al (USPN 5536508). Claims 1-5 are drawn to a pharmaceutical preparation of microcapsules of PLGA copolymer incorporating a peptide and citric acid ester. Claims 2 and 3 recite specific esters that are preferred for the embodiments of the claimed invention. Claim 5 recites the concentrations of lactic to glycolic acid present in the copolyme: of the claimed invention. Claims 6, 7 are drawn to the peptides of the claimed invention, naming them as LHRH analogues. Claims 8 and 9 are drawn to the peptide of claimed invention naming it as an analogue of somatostatine, octreotide. Claims 10 and 11 are also drawn to the peptide of the claimed invention reciting it to be an analogue of human calcitonine, salmon calcitonine.

Fuisz discloses essential elements of claims 1-5 and 8. The reference teaches a biodegradable controlled release formulation comprising a lactic/glycolic acid copolymer, encapsulated peptides LHRH, and additives triethyl and tributyl citrate (Abstract, column 6, lines 63-67; column 8, lines 40-42; column 10, lines 59-65; Table I). The reference also teaches percentage of claim 5 (Table I).

Though Fuisz discloses essential elements of the claimed invention, the reference is deficient. The reference discloses the encapsulation of a biodegradable copolymer, with peptides and additives, but is silent to the size of the encapsulations. The claimed invention is drawn to microcapsules, while the reference is drawn to capsules. The theory of encapsulating biodegradable copolymers to serve as carriers for active agents along with peptides and additives serving as plasticizers is present in the reference and is irrespective of the size of the encapsulation. Barring a showing of unexpected results, showing the criticality of the size restriction of *microcapsule*, the claimed invention is not patentably distinct from the prior art, and is obvious in view of it. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. Denied*, 469 U.S. 830, 225 USPQ 232 (1984), which held that devises having only differing dimensions, performing the same task, in the same way, the claims device was not patentably distinct from the prior art.

Another deficiency in the reference is its silence to the concentration of the citric acid ester. The reference discloses the presence of the plasticizers yet does not recite a specific concentration. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the plasticizer agent(s). However, the preparations of various pharmaceutical compositions having various amounts of the plasticizer is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

Yamamoto et al teaches essential elements of claims 5-7. The reference teaches a microcapsule sustained-release formulation comprising a biodegradable copolymer of lactic/glycolic acid, and a LHRH derivative, leuprolide (Abstract; column 2, lines 28-32; Examples 2, 4 and 5). The reference also teaches the concentrations of the claimed invention for the lactic/glycolic copolymer (column 5, lines 26-36).

Bodmer et al teaches essential elements of claims 5, 8 and 9. The reference teaches a microcapsule sustained-release formulation comprising a biodegradable copolymer of lactic/glycolic acid, and a somatostatine analogue, octreotide (Abstract; column 4, lines 18-25; Examples; claims1-5).

Canal et al teaches essential elements of claims 5, 10 and 11. The reference teaches a microcapsule sustained-release formulation comprising a biodegradable copolymer of lactic/glycolic acid, and a calcitonine analogue, salmon calcitonine (Abstract; column 4, lines 30-36; Examples 15 and T).

The only deficiency in these references (Yamamoto, Bodmer and Canal) is their absence of a citric acid ester as a plasticizing agent. The formulations of these inventions complete the same task of delivering various hormones over a delayed time period, and these formulations

also share the same degradable copolymer. One of ordinary skill in the art would have been motivated to combine any of the encapsulated peptides of Yamamoto, Bodmer or Canal with the formulation of Fuisz in order to impart differing therapeutic or prophylactic properties on the formulation. The peptide of Yamamoto would impart luteinizing properties, while the peptides of Bodmer would impart properties to inhibit insulin release. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings with the expected result of a sustain-release formulation useful in hormone therapy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-308-1235 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-5014.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
May 3, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600